RVD2007-06

Re-evaluation Decision

# Fenbutatin Oxide

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# Re-evaluation Decision

After a re-evaluation of the insecticide fenbutatin oxide, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is granting continued registration of fenbutatin oxide products for sale and use in Canada.

An evaluation of available scientific information found that products containing fenbutatin oxide do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of fenbutatin oxide uses, new risk-reduction measures must be included on the labels of products containing fenbutatin oxide.

The regulatory approach for the re-evaluation of fenbutatin oxide was first proposed in the consultation document[1] *Re-evaluation of Fenbutatin Oxide* (PACR2007-03). This Re-evaluation Decision document[2] describes this stage of the PMRA's regulatory process for the re-evaluation of fenbutatin oxide and summarizes the Agency's decision, the reasons for it and, in Appendix I, the comments received during the consultation process as well as the PMRA's response to these comments. This decision is consistent with the proposed re-evaluation decision stated in PACR2007-03. To comply with this decision, registrants of products containing fenbutatin oxide will be informed of the specific requirements affecting their product registration(s) and of regulatory options available to them.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act* (http://laws.justice.gc.ca/en/P-9.01/92455.html)

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act* (http://laws.justice.gc.ca/en/P-9.01/92455.html)

## What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA is re-evaluating older active ingredients and their uses to determine their continued acceptability in relation to human health, environment and value. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Fenbutatin oxide, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, there must exist a suitable foreign review that meets the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews, the PMRA will propose, under Program 1, a regulatory decision and appropriate risk reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account Canadian use patterns and issues (e.g. the Federal Toxic Substances Management Policy [TSMP]). A review of the chemistry of Canadian products is also conducted.

The USEPA conducted a re-evaluation of fenbutatin oxide and its conclusions were published in a 1994 RED. Tolerances were also reassessed and conclusions published in a 2002 Tolerance Reassessment Eligibility Decision (TRED).

## What is Fenbutatin Oxide?

Fenbutatin oxide is an insecticide used to control mites in greenhouse food and ornamental crops and for outdoor uses on ornamental nursery stock. The end-use products, formulated as wettable powders, can be applied in the greenhouse by conventional hydraulic handheld sprayers and outdoors with low volume ground boom equipment and backpack sprayers. Appendix II lists all fenbutatin oxide products that are registered under the authority of the *Pest Control Products Act*.

## Health Considerations

### Can Approved Uses of Fenbutatin Oxide Affect Human Health?

**Additional risk reduction measures are required on product labels containing fenbutatin oxide. Fenbutatin oxide is unlikely to affect your health when used according to revised label directions.**

Exposure to fenbutatin oxide may occur through consumption of food and water, while working as a mixer/loader/applicator or by entering treated sites. When assessing health risks, two key factors are considered: the levels where no health effects occur, and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that fenbutatin oxide was unlikely to affect human health provided that risk reduction measures were implemented. These conclusions were considered applicable to the Canadian situation and equivalent risk reduction measures are required.

### Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Fenbutatin oxide is currently registered in Canada for use on greenhouse cucumbers and tomatoes. As noted, fenbutatin oxide may be used on other crops in other countries which are imported into Canada. MRLs for fenbutatin oxide have been established for apples, citrus fruits, cucumbers, pears and tomatoes. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of the 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be promulgated.

## Environmental Considerations

### What Happens When Fenbutatin Oxide is Introduced Into the Environment?

**Additional risk reduction measures are required on the labels of products containing fenbutatin oxide. Fenbutatin oxide is unlikely to affect non-target organisms when used according to revised label directions.**

Non-target organisms (e.g. birds, mammals, insects, aquatic organisms and terrestrial plants) may be exposed to fenbutatin oxide in the environment. Environmental risk is assessed by the risk quotient method, in which a risk quotient (RQ) is calculated as the ratio of the estimated environmental concentration (EEC) to the relevant effects endpoint of concern. The resulting RQs are compared to corresponding levels of concern (LOCs). An RQ less than the LOC is considered a low risk to non-target organisms, whereas an RQ greater than the LOC indicates some degree of risk.

The USEPA concluded that reregistration of fenbutatin oxide was acceptable provided risk reduction measures to further protect the environment were implemented. These conclusions were considered applicable to the Canadian situation and equivalent risk reduction measures are required.

## Measures to Minimize Risk

Registered pesticide product labels contain specific directions for use which include risk reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of fenbutatin oxide, further risk reduction measures are required in addition to those already identified on existing product labels containing fenbutatin oxide. These additional measures are summarized as follows:

**Human Health**

- To protect handlers: additional protective equipment is required.
- To protect workers re-entering treated sites: re-entry is restricted.

**Environment**

- To reduce potential spray drift and runoff: additional advisory label statements.
- To protect non-target sensitive aquatic organisms and terrestrial plants: buffer zones for aquatic and terrestrial habitats.

Appendix III lists all required label amendments, including instructions related to basic hygiene practices.

## Other Information

Any person may file a notice of objection[3] regarding this decision on fenbutatin oxide within 60 days from the date of publication of this Re-evaluation Decision document. For more information on the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Requesting a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html), or contact the PMRA's Pest Management Information Service by phone (1-800-267-3615) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

[3] As per subsection 35(1) of the *Pest Control Products Act* (http://laws.justice.gc.ca/en/P-9.01/92455.html)

# Appendix I Comments and Responses

## 1.0 Comment on Buffer Zone Calculations - Spray quality:

Based on discussions with the Ontario Ministry of Agriculture Nursery Crops Specialist, the registrant has requested the PMRA use "medium" spray classification instead of "fine" to calculate buffer zones in the model, as this is more reflective of typical usage on ornamentals outdoors.

**Response:** The PMRA has recalculated buffer zones for fenbutatin oxide's use on outdoor ornamentals using the "medium" spray classification.

## 2.0 Comment on Aquatic Buffer Zone Calculations - Endpoints:

The registrant has requested a more appropriate endpoint be used in the calculation of aquatic buffer zones. A report provided by the registrant was the same one the USEPA considered in the determination of risk to the aquatic environment in the RED. However, the RED reported a Maximum Allowable Toxicant Concentration (MATC) of 0.31 ppb–0.61 ppb as the only endpoint. A no observed effect concentration (NOEC) value of 0.31 ug/L was reported in the study provided by the registrant.

**Response:** To provide a more accurate calculation of the aquatic buffer zones, the PMRA has recalculated the aquatic buffer zones using the NOEC from the submitted study instead of 1/10 of the MATC.

# Appendix II Current Canadian Registered Products Containing Fenbutatin Oxide as of 24 September 2007

| Registrant | Registration Number | Guarantee | Product name | Formulation Type | Class |
|---|---|---|---|---|---|
| E.I. DuPont Canada Company | 18594 | 98.4% | Technical Fenbutatin Oxide | dust | Technical Grade Active Ingredient |
| E.I. DuPont Canada Company | 16162 | 50% | Vendex 50WP Miticide | wettable powder | Commercial |
| Plant Products Co. Ltd. | 16309 | 50% | Vendex 50W Wettable Powder Miticide | wettable powder | Commercial |

# Appendix III Revised Label Amendments for Products Containing Fenbutatin Oxide

**NOTE:** This appendix does not identify all label requirements for individual end-use products such as first aid statements, disposal statements, precautionary statements and supplementary personal protective equipment that may be required. Additional information on labels for currently registered products should not be removed unless it contradicts information in this appendix.

Canadian end-use product labels must be amended to include the following to further protect human health and the environment.

**Add to "PRECAUTIONS"** section of the secondary display panel:

"Wear long-sleeve shirt and long pants, shoes plus socks, chemical resistant gloves, during application. In addition wear a NIOSH approved respirator and goggles during application with handheld equipment, when mixing and loading, cleanup or repair. In addition, during overhead application wear chemical resistant headgear."

"It is recommended that this product not be applied in a way that will contact workers or other persons, either directly or through drift. Only handlers wearing personal protective equipment may be in the area during application."

"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

"Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

"Users should remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

"If this pest control product is to be used on a commodity that may be exported to the US and you require information on acceptable residue levels in the US., contact 1-866-375-4648 or www.cropro.org/."

**Add to "DIRECTIONS FOR USE"** section of the Canadian labels:

"Do not enter or allow entry into treated areas during the restricted-entry interval (REI) of 12 hours. For hand activities involving high foliar contact, do not enter treated areas to perform such work until at least 48 hours have passed since application."

**Add to "ENVIRONMENTAL HAZARDS"** section of the secondary display panel of Canadian labels:

"Do not allow effluent from greenhouses containing this product to enter lakes, streams, ponds or other waters. For guidance contact the provincial Regulatory Agency."

**Add to "DIRECTIONS FOR USE"** section of the Canadian labels for outdoor use products:

Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.

**DO NOT** apply by air.

**Buffer zones:**

Use of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer, inter-row hooded sprayer, spot treatment, soil drench, and soil incorporation.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

| Method of application | Crop | Buffer Zones (metres) Required for the Protection of: | | | |
|---|---|---|---|---|---|
| | | Freshwater Habitat of Depths: | | Estuarine/Marine Habitats of Depths: | |
| | | Less than 1 m | Greater than 1 m | Less than 1 m | Greater than 1 m |
| Field sprayer* | Ornamentals and nursery stock | 30 | 4 | 10 | 5 |

* For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the canopy, the labelled buffer zone can be reduced by 30%.

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

"DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes."

**Add to "ENVIRONMENTAL HAZARDS"** section of the secondary display panel of labels for outdoor use:

"TOXIC to aquatic organisms. Observe buffer zones specified under DIRECTIONS FOR USE."

"To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include, but are not limited to: heavy rainfall, moderate to steep slope, bare soil, poorly draining soil (e.g. soils that are compacted, fine textured, or low in organic matter such as clay)."

"Avoid application of this product when heavy rain is forecast."

# Appendix IV Inputs to Buffer Zone Models

| Ground Use Data (from Canadian labels) | | | | |
|---|---|---|---|---|
| **Crop** | **Formulation Type** | **Method of Application** | **Number of Applications** | **Maximum Application Rate (g ai/ha)** |
| ornamentals | wettable powder | Field sprayer | 6 | 100 |

| Model Input Data for Aquatic Buffer Zones (from 1994 RED) | | |
|---|---|---|
| Half life for aquatic buffer zones | N A | *Assumed stable* |
| Most sensitive freshwater species | *Salmo gairdneri* (rainbow trout) | NOAEC = 0.31 µg/L |
| Most sensitive estuarine marine species | Eastern oyster | $EC_{50}$ = 0.2 µg/L |

## References

| PMRA Number | Reference |
|---|---|
| 1401252 | 1987. Early Life Stage Toxicity of Technical Vendex to Rainbow Trout (*Salmo Gairdneri*). HLR 460-87. MRID: 40473512. DACO: 9.5.3.1 |